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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,428	08/04/2006	Hiroshi Nagai	SHOBA6.001APC	9228

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KNOBBE MARTENS OLSON & BEAR LLP  
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EXAMINER
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PERREIRA, MELISSA JEAN

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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03/11/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/588,428	<b>Applicant(s)</b> NAGAI ET AL.	
	<b>Examiner</b> MELISSA PERREIRA	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/24/10 has been entered.

### ***Claims and Previous Rejections Status***

2. Claims 1,2 and 5-7 are pending in the application.
3. The rejection of claims 1,2 and 5-7 under 35 U.S.C. 103(a) as being unpatentable over Zeyuan et al. (*J. Agric. Food Chem.* **1998**, 46, 3875-3878) and Xia (CN1435125; derwent Acc No 2004-023802) in view of Suzuki et al. (*J. Agric. Food Chem.* **2000**, 48, 5649-5653) and in further view of Iwasaki et al. (US 7,014,876B2) is withdrawn.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1,2 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeyuan et al. (*J. Agric. Food Chem.* **1998**, 46, 3875-3878) in view of Suzuki et al. (*J. Agric. Food Chem.* **2000**, 48, 5649-5653) and in further view of Iwasaki et al. (US 7,014,876B2).
6. Zeyuan et al. (*J. Agric. Food Chem.* **1998**, 46, 3875-3878) discloses the method of reducing and examining blood triglyceride levels in a subject via the administration of black tea and green tea extracts/functional beverage (abstract; p3876, paragraph 2, results and discussion paragraph 1; p3877, paragraphs 2 and 3). The black tea and green tea extracts/functional beverage comprising catechins were prepared by boiling black tea for 5 min and subsequently filtering (p3876, Tea for Experiment and Sample Preparation).
7. Zeyuan et al. does not disclose the catechins of the instant claims, such as epigallocatechin-3-O-(3-O-methyl) gallate, etc. derived from the black tea leaves of the instant claims, such as Benihomare, etc.
8. Suzuki et al. (*J. Agric. Food Chem.* **2000**, 48, 5649-5653) discloses the extraction of O-methylated catechin derivatives, such as (-)-epigallocatechin-3-O-(3-O-methyl) gallate (EGCG3"Me) from the tea leaves of Benihomare cultivar (black tea), etc. (p5649, Introduction, paragraph 1). The black tea extracts of the disclosure were prepared with hot water for 30 min and are then subsequently filtered (p5650, Materials and Animals). The O-methylated catechin derivative EGCG3"Me and (-)-epigallocatechin-3-O-gallate (EGCG) extracts are orally administered to mice show analogous inhibition of type I and

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IV allergy (abstract; p5649, Introduction paragraphs 1 and 2; p5651, paragraphs 2 and 3).

9. Zeyuan et al. teaches that the constituents of black tea extracts comprising catechins reduce blood triglyceride levels and therefore at the time of the invention it would have been obvious to one ordinarily skilled in the art that the catechins, such as O-methylated catechin derivative EGCG3"Me of Suzuki et al. obtained from black tea (Benihomare cultivar) extract may be used in the black tea extract for the method of reducing blood triglyceride levels of Zeyuan et al.

10. Also, Suzuki et al. and Zeyuan et al. have identical extraction processes for the black tea extracts/functional beverage and therefore it would have been obvious to one skilled in the art that the black tea extracts/functional beverage of Zeyuan et al. may comprise O-methylated catechin derivatives as taught by Suzuki et al.

11. Suzuki et al. teaches that EGCG and EGCG3"Me have analogous properties and therefore, it is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect, such as reducing blood triglyceride levels.

12. Zeyuan et al. does not disclose the catechin concentration of the instant claims.

13. Iwasaki et al. (US 7,014,876B2) discloses a healthy drink containing catechins which are extracted from tea, such as Oolong tea, black tea (column 1, lines 66+; column 2, lines 32-53; column 8, lines 41+). The concentrated tea extracts are

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prepared by treating tea leaves with hot water (column 8, lines 41+). The catechins found in black tea are used in the healthy drink in an amount from 0.092 to 0.5 g per 100 ml (column2, lines 9-13; column 3, lines 16-20).

14. The disclosures of Suzuki et al., Zeyuan et al. and Iwasaki et al. are drawn to the same utility, such as a extracts of black tea containing catechins via adding hot water to tea leaves and therefore at the time of the invention it would have been obvious to one ordinarily skilled in the art to use the catechin extract concentration of Iwasaki et al. for the method of reducing blood triglyceride levels of Zeyuan et al. as the black tea extract will advantageously improve the function of the liver (Iwasaki et al.). In regards to the concentration of catechins found in the black tea extract, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.) to advantageously improve the function of the liver. It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

### ***Response to Arguments***

15. Applicant's arguments filed 2/24/10 have been fully considered but they are not persuasive.

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16. Applicant asserts that Zeyuan et al. does not disclose or suggest methylated catechins and does not indicate which substances in the extract has a BTG reducing effect. In addition, since the amount of catechins in the extract does not correlate with a BTG reducing effect, a person of ordinary skill in the art would not expect that catechins would contribute to the reduction of BTG.

17. The instant claims are not drawn to the method of reducing triglyceride levels in an individual by administering only the catechins of the instant claims but are drawn to the method of reducing triglyceride levels in an individual by administering a functional beverage which may comprise other constituents.

18. Although the amount of catechins in the extract of Zeyuan et al. does not correlate with BTG reducing effects it would have been obvious to one skilled in the art that the black tea extract/functional beverage of Zeyuan et al. and its constituents, such as the catechins are used for the method of reducing triglyceride levels in an individual. Suzuki et al. teaches that O-methylated catechin derivatives, such as (-)-epigallocatechin-3-O-(3-O-methyl) gallate (EGCG3"Me) are extracted from the tea leaves of Benihomare cultivar (black tea). Therefore, it would have been obvious to one skilled in the art that the EGCG3"Me of the black tea extract of Suzuki et al. may be used as a constituent of the black tea extracts/functional beverage of Zeyuan et al. for the method of reducing blood triglyceride levels.

19. The assertions with regard to the reference of Xia et al. are moot as the reference was omitted from the rejection.

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20. Applicant asserts that Suzuki et al. does not teach that EGCG3"Me and EGCG4"Me have BTG reducing effects.

21. The reference of Suzuki et al. was not used to teach that EGCG3"Me and EGCG4"Me have BTG reducing effects but was used to teach that O-methylated catechin derivatives, such as (-)- epigallocatechin-3-O-(3-O-methyl) gallate (EGCG3"Me) are extracted from the tea leaves of Benihomare cultivar (black tea), etc. Therefore, it would have been obvious to one skilled in the art that the EGCG3"Me of Suzuki et al. may be used as a constituent of the black tea extracts/functional beverage of Zeyuan et al. for the method of reducing blood triglyceride levels.

22. Applicant asserts that Iwasaki et al. does not teach that BTG levels are reduced by consuming a beverage containing 5 mg to 30 mg/100 mL of methylated catechins according to the instant claim 1.

23. Iwasaki et al. teaches that catechins found in black tea are used in the healthy drink in an amount from 0.092 to 0.5 g per 100 ml. Further, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.) to advantageously improve the function of the liver. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).



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24. Applicant asserts that although each of Zeyuan et al. and Iwasaki et al. disclose catechins extracted from tea leaves, the methylated catechins recited in the present claims are specific catechins which are present in large quantities in the specific tea leaves recited in the present claims and these methylated catechins differ from the catechins described in Zeyuan et al. and Iwasaki et al.

25. Zeyuan et al. and Iwasaki et al. teach of black tea extracts, not excluding those recited in the instant claims. Suzuki et al. teaches of black tea extracts of Benihomare cultivar comprising the O-methyl catechins of the instant claims and encompass the tea leaves of the instant claims and therefore have the same properties and are capable of the same functions, such as suppressing allergic rhinitis and effective for improving hyperlipidemia and gall bladder/liver functions.

### ***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/  
Examiner, Art Unit 1618